VZCZCXRO5446
PP RUEHCHI RUEHCN RUEHFK RUEHGH RUEHHM RUEHKSO RUEHPB
DE RUEHIN #1874/01 1530449
ZNY CCCCC ZZH
P 020449Z JUN 06
FM AIT TAIPEI
TO RUEHC/SECSTATE WASHDC PRIORITY 0462
INFO RUEHZU/ASIAN PACIFIC ECONOMIC COOPERATION COLLECTIVE PRIORITY
RUEHOO/CHINA POSTS COLLECTIVE PRIORITY

C O N F I D E N T I A L SECTION 01 OF 03 TAIPEI 001874

SIPDIS

SIPDIS

STATE FOR EAP/RSP/TC, STATE PASS USTR FOR DEPUTY USTR
BHATIA FROM DIRECTOR YOUNG

E.O. 12958: DECL: 05/26/2031
TAGS: ECON TW
SUBJECT: TAIWAN TIFA: SESSION 4: PHARMA AND MED DEVICES

REF: TAIPEI 1727

Classified By: AIT Deputy Director David J. Keegan, Reason 1.4 b

¶1. (C) Summary: The U.S. side requested that pharmaceutical price adjustments not be implemented until there were consultations to review both data and methodology, and a formal dialogue on healthcare system reform. Taiwan's Bureau of National Health Insurance (BNHI) stated its willingness to receive input from the U.S. side, but insisted that it lacked justification to significantly delay price adjustments. The Taiwan side was noncommittal regarding entering into a formal consultative dialogue on broader outstanding issues. This session concluded with the U.S. side noting that work at higher levels might be needed to narrow the differences. End summary.

¶2. (C) The Fifth U.S.-Taiwan TIFA meetings led by Deputy U.S. Trade Representative (DUSTR) Ambassador Karan Bhatia took place in Taipei on May 25 and 26, 2006. This cable reports on Session 4, which covered pharmaceutical and medical device issues. This session was co-chaired by Deputy Assistant U.S. Trade Representative (DAUSTR) Eric Altbach and Franco Huang (Chih-Peng), Director General (DG), Bureau of Foreign Trade (BOFT), Ministry of Economic Affairs (MOEA).

¶3. (C) Altbach opened by saying the U.S. side attached great importance to the issues under discussion. He stated that, while there is progress to report in many areas, pharmaceutical policy is one of the principal area in which we have not made progress in narrowing our differences. He noted that the U.S. pharmaceutical industry is among the most engaged in monitoring U.S.-Taiwan economic and trade relations and that the U.S. industry believes that its prospects in Taiwan are getting worse. Altbach added that our relationship in this area was deteriorating and that it is important to make sincere efforts in resolving outstanding problems.

¶4. (C) Altbach offered two proposals to resolve outstanding problems in this area: 1) That price adjustments resulting from the fifth Price/Volume Survey (PVS) not be implemented until the two sides can consult to review the data and improve the methodology; and 2) That the two sides agree to undertake a formal dialogue covering the broader issues of health care system reform with participation of AIT, TECRO and private sector stakeholders. Altbach pointed out that these proposals would not simply benefit U.S. industry, but are also good for Taiwan patients and for the financial well-being of Taiwan's healthcare system.

Price Volume Survey

¶5. (C) Altbach specifically noted that a standstill of the

PVS pending a thorough review of the survey's methodology with AIT, TECRO and industry would enhance the credibility of the PVS findings. He concluded by noting that the TIFA pre-meetings had failed to advance the agenda and that an unsuccessful outcome would result in a failing grade for the pharmaceutical session.

¶6. (C) Altbach then offered to "recast" our request for a standstill in a way that preserves the substance of the proposal but in language that might help the Taiwan side to engage. The request was revised to read that implementation of the price cuts not take place until both sides have undertaken a "thorough review," which:

-would require "some time";
-would cover both validity of the data and the underlying methodology;
-would involve consultations with AIT and private sector stakeholders, including innovative, research-based pharmaceutical companies; and
-would involve a review of the R-zone and the therapeutic groupings

¶7. (C) Bureau of National Health Insurance (BNHI) Vice President (VP) Lee Cheng Hua responded as follows:

-The BNHI had erceived many critical assessments of the PVS including the American Chamber of Commerce's White Paper, which focused on the black hole, price discrepancy phenomenon.

-He said that the PVS had taken place four times and industry such as Pharma and IRPMA were always involved in the process. He also said that AMCHAM, IRPMA, and U.S. Pharma were always welcome to comment on current and future PVS.

-He maintained that the fifth and current PVS was ongoing and there was not enough evidence or data from the U.S. that problems were widespread.

-Using dubious logic, Lee claimed that the PVS procedure provides special consideration for patented products. All the patented products are sourced from abroad and therefore, Lee incredibly claimed, no action by Taiwan generic manufacturers can negatively impact the imported patented drugs.

-Lee also proclaimed BNHI would like to improve the paperwork and would respond to companies who had specific questions about therapeutic grouping.

-If anyone reports improper pricing of off-patent compounds BNHI will request the competent authorities to undertake a formal investigation.

-Lee concluded that BNHI was trying to close the black hole and get to actual transaction pricing (ATP) which is what U.S. Pharma has also been seeking. Lee produced several statistics that he said demonstrated the success of U.S. pharmaceuticals in Taiwan, including that the percentage of patented products had increased from 15 to 30 percent of imports over the past 9 years and that the total market share for imports had increased from 50 to 60 percent.

¶8. (C) Altbach reiterated the U.S. continues to have concerns over methodology. He then asked Lee to confirm whether they would hold to the July 1 implementation date.

¶9. (C) VP Lee stated that the PVS was scheduled for July, but if industry had concerns BNHI could take this into account, noting that this may result in a delay of a few weeks. He stated that the timing was not an absolute but that the PVS price adjustments would be implemented on time with consensus from industry. He noted that in the past BNHI has generally consulted directly with individual U.S. firms,

but in the future they would be happy to include AIT, AMCHAM and PHARMA in discussions about PVS.

¶10. (C) Altbach responded that just receiving concerns was insufficient and that industry's concerns needed to be addressed. He noted that U.S. industry would not be able to provide a comprehensive set of proposals by July 1.

¶11. (C) VP Lee replied that they would like more specific input from the U.S. side. Otherwise any BNHI action to delay the PVS would be unfounded. He asked for details on the concerns of the U.S. industry with the methodology of the PVS.

¶12. (C) Altbach noted that he could ask U.S. industry to produce more specific written input. But he noted that if our industry thinks this exercise is just pro-forma and that BNHI intends to implement the adjustment in July regardless then this would be seen as a "failed outcome of TIFA." Altbach said that what we require from BNHI is 1) a timeframe for the review and 2) an acknowledgement that the price adjustment would not take place until the review is completed and necessary reforms implemented. Pressed by VP Lee as to how much time the U.S. side wanted, Altbach said as much time as would be necessary for a thorough review, given the seriousness of the issues, perhaps one year.

¶13. (C) VP Lee responded that he could not answer at this time. He suggested that AIT ECON and COMM may be able to help with the review process.

¶14. (C) Altbach responded that perhaps higher level intervention may be needed at this point and reemphasized that it is necessary to move forward on other issues such as the R-zone and therapeutic grouping, as well as on implementing the more formal dialogue on issues such as SPD (separation of prescribing and dispensing) and ATP (actual transaction pricing).

¶15. (C) DG Huang offered an alternate option. He proposed a two-stage process: 1) continue the PVS, while accepting comments for the viability of data with a high probability of a time delay; and 2) regularly obtain industry input for the next PVS. He noted both sides wanted to narrow the price gap, but the PVS had been publicly announced and approved and must be seen as being on schedule. He inquired if this type of understanding and language was acceptable.

¶16. (C) Altbach replied that while the TIFA public outcome statement is fully open to negotiation, a commitment to

regular meetings on how to improve the PVS by instituting a fair and transparent system acceptable to all concerns was paramount. There should be a common understanding between the U.S. and Taiwan on the need for a delay of the fifth PVS. He urged that sufficient time be allocated for industry to prepare its concerns, for BNHI to conduct its analysis and implement the results.

¶17. (C) DG Franco Huang interjected that VP Lee was not authorized to address any changes to the timing of the PVS. He noted that time was short, but he was hoping that acceptable language could be found for the TIFA outcomes statement. Altbach and DG Huang agreed that this discussion would need to go to higher levels.

Formal Healthcare Dialogue

¶18. (C) Altbach proposed establishing a formal, ongoing dialogue on healthcare regulatory and financing issues such as PVS, separation of prescribing and dispensing (SPD), actual transaction pricing (ATP) and other issues. This dialogue would include AIT, TECRO and the private sector.

¶19. (C) U.S. Department of Commerce (USDOC) Office Director

of Taiwan and Korean Affairs Brenda Carter-Nixon initiated discussion on SPD noting that its implementation was the first step in eliminating the black hole. Carter-Nixon also called for an explanation of the regulatory requirement for SPD. Taiwan Bureau of Pharmaceutical Affairs (BOPA) Director General (DG) Chi-Chou Liao responded that this was a systemic problem, that ATP is needed to resolve the issue. Carter-Nixon noted that the motivation to over prescribe was based on profit incentives rather than medical need.

¶20. (C) VP Lee said U.S. health maintenance organizations have clinics as well as pharmacies. He stated that U.S. firms would bear the brunt of the changes if SPD was implemented in Taiwan because most of U.S. pharmaceutical sales are to large hospitals. He did note that if a pharmacy is located next to a clinic, it must be able to prove the clinic is not involved in its business.

¶21. (C) Altbach again noted that this topic was good candidate for discussin in a formal dialogue process to exchange experiences from the two systems. VP Lee replied that BNHI was open to talk to anyone as they always have been. (Comment: Though specifically asked several times, VP Lee did not directly respond to the request for formal dialogue. End Comment)

Patent Linkage - Movement

¶22. (C) Altbach briefly noted that a separate discussion had reached agreement to hold discussions on how to move toward a patent linkage system and to send two Taiwan officials to the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (PTO) for training on the U.S. patent-linkage process.

¶23. (C) Altbach concluded the session by reviewing the positions and stating that dialogue between senior officials might be necessary in order to resolve differences.

¶24. (U) This cable was reviewed by USTR prior to transmission.
YOUNG